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ABSTRACT

This paper summarizes the rules and regulations under which educational researchers are expected to operate. The role of the Institutional Review Board (IRB) in ensuring protection of research participants from unethical procedures or investigators is discussed, as is the general exemption of specific types of educational research from the IRB review process. Among the issues discussed are maintenance of subject anonymity and/or confidentiality in the light of data processing capabilities of current technology; implications of the proposed Grassley Amendment requiring parental consent for seven types of research, and the Family Privacy Protection Act of 1995. Responses of the IRB at Illinois State University (ISU) to these issues is reviewed, noting development of a set of procedures. Specific issues addressed by the ISU Board include: what it means to be "exempt"; distinguishing between teaching and research when research is conducted in conjunction with a class; the use of audio and video technologies; and the impact of new legislative restrictions. (DB)

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The Institutional Review Board in Social Science Research

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Abstract

How to ethically treat the human participants of medical research has been a on-going discussion for centuries. Less talked about, unfortunately, is how participants of social science research, especially of the kind of research typically found in educational settings, are protected from unethical procedures or investigators. Title 45 of the U.S. Code of Federal Regulations, Part 46, contains provisions allowing educational research to generally be exempt from Institutional Review Board review process. Recent legislative movements, together with rapidly changing technologies, are causing many researchers to rethink the practicality of this traditional exemption. This paper summarizes the rules and regulations under which educational researchers are expected to operate. The role of the Institutional Review Board (IRB) is discussed, and recent legislative imperatives are introduced. Finally, how one university addresses these challenges to the educational research process is presented.

The Institutional Review Board in Social Science Research

In response to a number of research experiments that had mistreated research subjects the National Research Act, enacted on July 12th of 1974, established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges of this commission was to develop ethical principles and guidelines for researchers to follow in the conduct of research involving human subjects. One of their key reports, know as The Belmont Report (Appendix A), became the basework of many guidelines that followed.

The Public Health Service Act (as amended in 1985 by P.L. 99-158 and in 1993 by P.L. 103-43) called for the creation of regulations that would establish Institutional Review Boards (IRBs). Through the Department of Health and Human Services these laws were codified into the Code of Federal Regulations Title 45: Public Welfare, Part 46: Protection of Human Subjects (Appendix B). In the intervening years over 50 federal agencies, including the National Institutes of Health and the Office for Protection from Research Risks, have agreed to have research conducted for or sponsored by their agencies adhere to the rules stated in 45CFR46. Some agencies, like the Food and Drug Administration, have created additional regulations that apply to particulars that agency must address (such as the development and approval of new drugs, medical devices, and procedures).

A key facet of this legislation, and the ensuing regulation, was the requirement for institutions conducting federally funded research to have and maintain Institutional Review Boards. The IRBs were given the authority to "review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy" (45 CFR § 46.109). IRBs were specifically to: assess the risks associated with a research effort in relationship to the benefits to be gained, insure for an equitable selection of subjects, and determine that informed consent, including the informed assent of minors and those unable to grant informed consent, of the human participants was to be obtained and appropriately documented. During the mid- to late-1980s most institutions of higher learning established IRBs and began applying the rules of 45CFR46 to the research conducted on their campus or by their faculty and/or staff.

Recognizing that certain types of research typically posed little risk to the subjects, and were already commonplace in our society, the regulations established six categories of research that were to be "exempt from this policy". Included in this exemption were the following paragraphs that are of particular interest to educational researchers:

> (1) Research conducted is established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

> (i) information obtained is recorded in such a manner than human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observations of public behavior that is not exempt under paragraph (b)(2) of this section if:

> (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (45 CFR §46.101)

Although these components of the regulation would seem to make most, if not all, educational research exempt from the IRB process that is rarely the case. Additional sections in the regulation call for specific protection to be afforded to children, especially those of diminished capacity (Subpart D, 45 CFR §46.401 through .409). Other sections require a greater degree of IRB review of proposed research if the investigator is to record data using either an audio recorded (an expedited review process, 45 CFR §46.110) or a video recorder (a full review process). Further, questions have arisen through the research and educational communities concerning several critical terms in the aforementioned sections. For example, what is a "commonly accepted educational setting", and when is a practice a "normal educational practice"?

For the past two decades educational researchers have been trying to find means to work within these scope of these regulations. Grotberg in 1979 described the building resistance by educational researchers to complying with the new regulations. In 1983, Lyons wrote to rural educators about these regulations, giving suggestions for how to completed IRB proposal forms. As recently as 1993 the discussion continues (Howe and Dougherty, 1993). The intersection of local practice and custom, federal and state regulation, and a desire on the parts of researchers and practitioners alike to advance the field of knowledge while acting in a professional and ethical manner seem to have created more questions than answers.

These issues embodied by the principles of The Belmont Report and 45CFR46 are still not universally decided, nor even well understood, by many educational researchers and practitioners alike. Unfortunately two new issues have recently entered the discussion, issues which are likely to make it even harder for educational researchers and subjects alike. The first of these issues concerns technological innovations, while the second involves new legislative requirements.

The New Technology

In the late 1970s and early 1980s, when most of the laws and regulations that we follow today were written, the computer revolution of the past few years was only a dream in certain entrepreneurs minds. At that time computers were either massive devices requiring extensive support systems and training, or they were expensive toys that were mostly the purview of the electronic hobbyist. Sound was still being recorded on reel-to-reel tape recorders, with 8-track tapes typical and the smaller cassettes just beginning to make a headway into the marketplace. Home VCRs were likewise beginning to enter the market although the revolution in miniaturization that would bring us 8mm cassettes and micro-sized camcorders was still many years away. Arpanet, the forerunner to the Internet, was still a small, closed system used by just a few university researchers and the government.

Today, however, all of this has changed. Computers have become powerful machines capable of executing many different tasks simultaneously. They have also become commonplace, taking an increasing share of personal and educational budgets each year. The explosive growth of the Internet allows students and teachers both to access information from a world away at the touch of fingertip. Improvements in electronics have given us the microcassette audio recorder, palm-sized video camcorders, and radio-transmitting microphones that are so small as to be almost undetectable. The days of a field researcher being concerned about disturbing his or her subjects with their presence and/or audio or video recording equipment are rapidly passing. Indeed, the very act of eavesdropping on a conversation or personal interaction, recording it for later analysis and study, is no longer the technical problem it once was.

In this same period the literature shows an geometric increase in the number of social science researchers who are turning to these technologies as a way to record data gathered from human subjects. Methods being reported range from the typical (using an audio recorder for interviews or a camcorder for capturing behaviors) to the novel (interacting with subjects through electronic mail messages). The presentation of data is also changing, as researchers turn back to these new technologies for conveying the important messages gathered through their studies. It is not unusual to attend a regional or national meeting where a researcher no longer just reads the findings from his or her study but will display photographs, audio or video recordings, or electronic interactions as part of their presentation.

Such tools seem to make the job of the educational researcher easier while also providing a richer context for communication and presentation. But do our subjects realize that this is what we are doing with their voices, their pictures, and their writings? Can a subject remain truly anonymous, and what does it mean to insure a subject of his or her confidentiality, given the expanding role of research technology?

The New Legislation

On March 31, 1994 section 445 of Title 20, United States Code, part 1232h, was amended to provide additional protection for pupil rights (Appendix C). Generally known as the "Grassley Amendment", after Senator Charles E. Grassley (R-IA), these provisions require the prior written consent of parents for research conducted with children in schools that was funded by the Department of Education. Any "survey, analysis, or evaluation" that asked for information in seven specific areas of concern would be covered by this policy. Further, all "instructional materials, including teacher's manuals, films, tapes, or other supplementary materials which will be used in connection with any survey ... shall be available for inspection by the parents or guardians of the children."

Researchers not involved in Department of Education funded studies probably have not heard much about this new law. Regulations currently being proposed by the Department to implement the new law would narrow the application of the regulation only to surveys and studies given to students in elementary and secondary education, not in higher education (Human Research Report, 1995). Apparently these proposed regulations, which are still in their comment period (until October 27, 1995), have angered the Senator, a spokesman for whom was quoted as saying "the effect of the regulations is to gut the intent of the amendment".

Since that time new legislation has been passed by the House of Representatives and is currently under consideration in the Senate. Known as H.R. 1271, the Family Privacy Protection Act of 1995, this bill seeks to make provisions similar to those already enacted apply to all research, whether funded by the Department of Education or not (Appendix D). In addition to requiring written consent from parents prior to a child participating in a survey or interview, this new legislation has the potential for eliminating all forms of "passive consent". Further, this new regulation would apply if the program/school received any kind of federal funding at all.

> In effect, what this means for parents is that they no longer have to prove that the specific activity that they find offensive is federally funded. They no longer have to show that it is a research or experimentation program or that it is a psychiatric or psychological test with the primary purpose of revealing private information. They must simply show that the survey, analysis, or evaluation revealed private information, that it was in a federally funded program, and that their consent was not obtained. This is much easier for a parent to demonstrate and will thus provide wider protection for parents and students. (Human Research Report, 1995, p. 6)

How will researchers be able to conduct survey, observation, and interview kinds of research on children dealing with sensitive areas if parents must consent in writing prior to each interaction? In addition to the added time and increased cost required to obtain such written consents researchers might find their subject pools reduced in number and/or skewed or restricted. This might be especially bothersome in studies that deal with sexual behaviors/AIDS, child abuse or neglect, and the like. Of additional concern is the feeling that this legislation would mandate outside of the regular IRB process. Rather than allowing a researcher to present

the case for their research to an impartial panel of local experts and citizens all such research would be subject to the same requirements, whether they are in fact useful or detrimental.

Issues for Researchers and Institutional Review Boards

For the last year members of the Institutional Review Board at Illinois State University have been considering these issues. What has resulted from these musing is a set of procedures that, so far, seem to work well in addressing the kinds of research being conducted at ISU. As the IRB process is intended to reflect local norms and attitudes in addition to scientific accuracy these procedures should not be read as being suitable for every institution or researcher. Rather, they are intended to provoke further thought and discussion on these evolving issues.

The Institutional Review Board at Illinois State University is a two-tiered structure. The Executive Committee, meeting at least once each month, consists of fourteen members appointed by the President of the University on rotating three-year terms. These members are: the IRB Chair, a representative (non-voting) from the University Research Office, a physician, a lay member volunteer from the community who is normally unaffiliated with the university, and two faculty members selected from the each of the five academic colleges. Each academic department and administrative unit also appoints a Department/Unit Representative. Proposals submitted from individual researchers are first read by their Department/Unit Representative and are then forwarded to the Executive Committee. Different routing paths exist depending on if the proposal has been classified by the Department/Unit Representative for Exempt Review, Expedited Review, or Full Review. Processing over 350 new research proposals each year, the ISU IRB's procedure ensures at least two impartial readers for each proposal with responses made to principal investigators in under one week on over 90% of proposals submitted.

What does it mean to be "exempt"?

One of the first issues the IRB faced was what it meant to be "exempt from further review". It was clear that the regulations were crafted so as to not create an undue burden on typical process, especially those found in educational settings. By the same token the regulation contains ambiguities and conflicts, especially when utilizing children or other vulnerable populations. Should a principal investigator be allowed to decide if their research is exempt from review, or would a principal investigator potentially be too close, too biased, to give a fair appraisal? In considering this issue the ISU IRB decided that all research involving human subjects must be submitted and reviewed. In doing so the IRB took the position that only impartial readers, those not directly involved in the research, could make the determination.

Recognizing the potential burden placed on researchers the IRB also crafted a submission form and process that is easy for the principal investigator to complete and provides a rapid response to their application. The typical IRB Proposal Submission (see Appendix E for a sample guidelines and application form) that is eventually classified as exempt is written in under one page of text. These applications are read by two independent readers (the submitter's Department/Unit IRB Representative and the IRB Chair) before approval is given. In most cases this process takes only a few days to complete. Every so often, however, a proposal that is

submitted as exempt by / the investigator turns out to involve issues that, under the regulation, disqualify it for exempt (consideration. In those cases either the Department/Unit Representative and/or the IRB Chair wiill either speak with the principal investigator about potential revisions and/or "bump" the propoosal to either an Expedited Review or Full Review process.

When is it teaching and l when is it research?

Another issue thhat frequently confronts university-based IRBs involves research conducted in conjunctioon with a class. Variations on this theme range from studies conducted within the confines of thhe classroom solely to used for classroom exercises to studies where the students, acting as reseaarchers, collect data in the field with the hope of writing a paper and presenting their findinggs. A quick read of the regulation might lead one to believe that, unless the study were to contrihbute to "generalizable knowledge" (as stated in the regulation), it was not to be considered researcch. Many define generalizable knowledge as a result of publishing a paper in a journal or preesenting it at a meeting. If data is to be collected but the intent is not to publish or present is thee activity considered research and, therefore, subject to the IRB review process?

The Illinois Statte University IRB took a somewhat different look at this issue. Rather than considering what wwas to be done with the product of the research effort (the paper or the presentation) the IRB cconsidered the activity itself. The intention of the research may be, initially, not to publish (or present his or her data; however, once it has been collected it might look better than initiallyy intended and be suitable for such purposes. On the other hand a researcher might have eevery intention of publishing or presenting findings but, due to unsympathetic revieweers or editors be unable to find an appropriate outlet for their work. The end product of the reseaarch effort is, oftentimes, not under the direct control of the principal investigator.

The research acttivities, however, are under the investigator's control. Whether that investigator is a studentt or a teacher, in a classroom or in the field, they have a responsibility to behave in an ethical anod professional manner. At Illinois State University, as at most universities, proceduress exist to insure the fair treatment of students by faculty in classes and other academic venturees. Appropriate codes of conduct can be found for both faculty and students, and mechanisms exist for investigating and adjudicating complaints of faculty against students and students aagainst faculty. Oftentimes the syllabus and class handouts serve as a quasi-contract betweenn a faculty and the students enrolled in a class as to what activities are expected, and what graades will be awarded, in a particular class. Within the confines of a class, then, there appears to bbe adequate provisions for protecting the rights of all individuals involved. Whether it happens wititthin the physical classroom or outside both faculty and students have an academic responsibilityy and obligation to behave in certain ways.

Such protectionns, however, are not found when a faculty or student actively encounters individuals not enrolleed in the class. An outsider is most likely unfamiliar with the requirements of the course, the particcular assignment being accomplished, or the protections available through academic channels. Fuurther, if the activity is a research activity -- one where an systematic

observation or interaction is made of human subjects in a naturally occurring or purposefully manipulated condition -- those human subjects may be totally unaware of their participation. For these reasons the ISU IRB has defined teaching as an activity that occurs between and among students and teachers. If the activity is to be a research activity (as defined above) but is to take place solely among the students and teachers as part of a recognized instructional process, where the students and teachers all know of the design and purpose (such as through a syllabus or handout), the activity is not considered research for IRB purposes. If, on the other hand, the activity is to involve individuals not students or faculty in the course, or is to involve activities where the students and/or teachers are unaware of their participation (such as a faculty systematically studying their students' responses to manipulated conditions) the activity would be considered research and subject to IRB review and approval.

What about, then, activities like student teaching and corporate internships? Although these activities involve individuals beyond the students and teachers there is a clear sense and understanding by all involved that such activities are for the training of the students and not for systematic investigation or research. In these cases the IRB encourages clear communication of purposes and intents among all participating individuals so that everyone understands the nature and extent of the activity's interactions. These activities, however, are not research and are not reviewed in any way by the ISU IRB. One final note: on occasion an individual involved in a student teaching practicum or corporate internship wants to conduct research as a part of their other experiences. While the thrust of the primary activity is not research that additional activity would be and, therefore, would require a proposal submission to the IRB.

What about the use of audio and video technologies?

The use of new technologies is posing questions for which there are no clear or definitive answers. Computer, audio, and video recording technologies may be used as an integral part of a research project or may just serve as an ancillary means of recording data. While the regulation mandates and Expedited Review process for studies using audio recordings nothing is stated about video or computer technologies.

During the past year the ISU IRB has consistently taken the position that it is not the technology that is necessarily of interest but rather the degree to which an human subject surrenders their privacy, their right to confidentiality. Research processes that involve technologies likely to reduce privacy are given a more stringent review than those less likely to intrude upon personal space and information. Thus, studies which involve only handwritten notes taken by the researcher without reference to an individual's name or other identification generally qualify for Exempt Review. Studies that use an audio recorder where a person's voice might be identified or a computer record where an individual's name is stated generally qualify for an Expedited Review. Those studies using procedures and/or technology where the identification of an individual subject is relatively easy, such as through the use of a video recording, are afforded a Full Review.

This is not to say that these types of data collection methodologies and technologies make the studies more risky for the human participants. The actual degree of risk might be very small.

Rather, it is the methodology and technology that could be used to ends not well understood by the human subject. The ISU IRB requires the researcher, when using such methods and technologies, to discuss how they will maintain the privacy of the individual and the confidentiality of the data that is collected. If, for example, a video tape record is to be kept and shown by the researcher as part of a presentation from the study the researcher must make that intent clearly known to the subjects as part of the informed consent process. The increased level of review by the IRB insure that these considerations and protections are made.

What about H.R.1271?

Unfortunately, this is one area for which there are no clear-cut answers. Clearly new legislation and regulation will have to be incorporated into the overall IRB process in order to be effective. At the same time it appears that, while these new rules are well-intended, these rules can create absolute boundaries which can serve to inhibit important social science research. While the exact impact will have to wait for the final legislation to approved and regulations to be written, the ISU IRB is in general agreement with a statement issued by the American Psychological Association and endorsed by other research organizations nationwide:

> APA and several other organizations representing social and behavioral scientists feel that this legislation is unnecessary and will make federal research results less reliable. Research findings indicate that a lack of parental response to written consent requests is rarely due to objection to their child's participation, yet a requirement for written consent can reduce the pool of appropriate participants by half. Moreover, survey research focused on such areas as substance abuse, adolescent pregnancy and violence would be more difficult to conduct, thus limiting out ability to assess the needs of children and adolescents.
>
> An absolute requirement of written consent does not benefit the children or parents it purports to protect. Such a requirement undermines the authority, knowledge, and wisdom of the Institutional Review Board. In fulfilling their charge to protect research participants, the IRB is authorized and designed to take into account individual protocol requirements and the composition and standards of the local community. IRBs and investigators work together to conduct research that is scientifically valid and ethically sound. (APA position on the family privacy protection act of 1995, 1995, p. 213-214)

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